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AMGEN

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Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Reference Docket No. 00D-1033

Dear Sir/Madam:

Amgen appreciates the opportunity to comment on FDA's draft guidance for industry entitled "Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank" published in the March 29th, 2000 issue of the Federal Register. The comments provided address a number of questions and concerns with respect to FDA's implementation plan for the clinical trials data bank. Amgen respectfully requests FDA's consideration of the points raised in its implementation and administration of the clinical trials data bank discussed in the draft guidance document

The FDA Modernization Act (Public Law 105-115) mandated that the Secretary of Health and Human Services, acting through the Director of NIH, to establish, maintain, and operate a data bank of information on clinical trials for drugs intended to treat serious or life-threatening diseases. Amgen agrees that the draft guidance establishes the framework for such a database and defines the types of data sponsors of protocols for serious or life-threatening diseases will be required to submit along with the timeframes for its submission. The guidance does not, however, address the format for data submission. We believe it would be of benefit for FDA or NIH to develop a standardized format for data submission. To streamline the process, a standardized form, analogous to FDA forms 1571 or 1572, could be developed to comply with the guidance. The standardized form should be made available electronically.

The draft guidance states that a second guidance document will be issued providing details on implementation of the data bank. Amgen has the following questions/concerns with respect to FDA's implementation of the clinical trials data bank:

1. It is our interpretation that this regulation is meant to apply to U.S. studies only. We suggest that FDA clarify that sponsors be required to submit data for studies of drugs intended to treat a serious or life-threatening disease conducted within the US, and that the stipulation regarding coordination of

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2. data banks (section II of the guidance) applies only to those data banks within the U.S.

2. Section III D on page 4 of the draft guidance states the following:

> "Section 113 of the Modernization Act specifies that the data bank will not include information relating to a trial if the sponsor certifies to the Secretary of DHHS that disclosure of the information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary makes a determination to the contrary. The Secretary will make a final determination on the sponsor's waiver request, and if the Secretary determines that such disclosure would ***not*** substantially interfere with enrollment, the trial is to be included in the Clinical Trials Data Bank".

Amgen believes the guidance should specifically address the criteria the Secretary will use in determining whether or not a waiver should be granted. Additionally, the guidance should allow the Secretary to grant a waiver if public disclosure of information on a drug being tested in a serious or life-threatening disease setting would require the release of confidential commercial or trade secret information, or would cause a sponsor to lose its competitive advantage. Commercial harm could easily occur since companies frequently compete in the development of the same or similar compounds or in areas which involve patent challenges

3. Section V, page 5 of the draft guidance, cites section 113 of the Modernization Act, and indicates information on trials for serious or life threatening diseases will be entered into the clinical trials data bank either with the consent of the sponsor or when a trial to test effectiveness begins. Please clarify whether this statement means that if a sponsor does not submit the requested data within the timeframe specified in the guidance, FDA will enter the information without consent of the sponsor.

We hope the above comments are helpful to FDA in its efforts to finalize its draft clinical trials data bank guidance and in its drafting of the corresponding implementation plan. I may be reached at 805 447 3058 should you require clarification on any of the points raised in Amgen's comments.

Sincerely,

Ralph Smalling
Vice President Regulatory/Medical Affairs

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